UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON,
PLAINTIFF,

V.

CIVIL ACTION NO. 3:17-01362

AMERISOURCEBERGEN DRUG CORPORATION, ET AL.,
DEFENDANTS.

CABELL COUNTY COMMISSION,
PLAINTIFF,

V.

CIVIL ACTION NO. 3:17-01665

AMERISOURCEBERGEN DRUG CORPORATION, ET AL.,
DEFENDANTS.

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT CONCERNING DEFENDANTS' STATUTORY AND REGULATORY DUTIES

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Plaintiffs, The City of Huntington and Cabell County Commission (collectively, "Plaintiffs"), submit this motion concerning Defendants' statutory and regulatory duties under the federal Controlled Substances Act 21 U.S.C. §§ 801 *et seq*., and the West Virginia Controlled Substances Act ("WVCSA"), W.Va. Code §§ 60A-8-1 *et seq*.

Plaintiffs have previously filed a Motion to Adopt Multidistrict Litigation Court's Order on Defendants' Controlled Substances Act Duties,[1] which seeks for the Court to adopt as law of the case the August 19, 2019 ruling of the U.S. District Court for the Northern District of Ohio, Hon. Dan A. Polster, U.S.D.J. (the "MDL Court") – with regard to Defendants' claims under the federal Controlled Substances Act in this remanded action.[2] Defendants have opposed that motion which remains pending.

While Plaintiffs continue to believe it is appropriate to adopt Judge Polster's ruling based on the law of the case doctrine, the ruling constitutes a correct interpretation of the law, and, furthermore, its reasoning compels a similar holding when interpreting the WVCSA. Consequently, Plaintiffs now seek an order granting partial summary judgment holding that in order to carry out the mandate of the CSA and the WVCSA to maintain effective controls against diversion, Defendants are under a duty to refrain from shipping suspicious orders that have not been cleared

[1] *See* Docs. 189 (motion), 190 (memorandum).

[2] See Order Doc. 2483 (attached herein as Exhibit A). In the CSA Ruling, the MDL Court granted the Ohio bellwether Plaintiffs' motion for partial summary judgment with respect to Defendants' duties under the CSA. Plaintiffs' memorandum of law sets forth that under "law of the case" principles, rulings of the MDL Court should not be revisited absent changed or unusual circumstances and further requests that this Court adopt the MDL Court's CSA Ruling.

through investigation; instead, they must block those orders until they can determine that diversion is unlikely.

INTRODUCTION

Distributors are subject to regulation under the federal CSA and the WVCSA. Both are relevant to Plaintiffs' public nuisance claim. In particular, Defendants' violation of various statutory and regulatory norms is relevant to establishing that their conduct created and constitutes a public nuisance. The parties do not agree, however, on what the CSA and the WVCSA require distributors to do with respect to "suspicious orders." Thus, before the Court can adjudicate any factual disputes as to Defendants' compliance with their statutory and regulatory obligations (or even determine whether there are such factual disputes), it will be necessary to determine what the statutes and regulations require. Through this motion, Plaintiffs seek summary adjudication of those legal questions.

The CSA and the WVCSA both require distributors of opioids to maintain "effective controls against diversion."[3] Pursuant to regulations adopted by the federal Drug Enforcement Administration ("DEA"), the agency charged with administration of the CSA, the maintenance of such controls requires registrants to design and operate a system for identifying and reporting suspicious orders.[4] One of the disputes at issue in this motion concerns the further duty to refrain from shipping suspicious orders until the registrant can determine, through investigation and due diligence,

[3] 21 U.S.C. § 823(b)(1); W.Va. Code §60A-3-303(a)(1).

[4] *See* 21 C.F.R. § 1301.71(a)-(b); W.Va. C.S.R. § 15-2-4.4, superseded by W. Va. C.S.R. § 15-2-5.3 (Apr. 1, 2020).

that the order is not likely to be diverted. As described below, the DEA has construed the CSA to impose this duty because a registrant's controls against diversion will not be effective if orders identified and reported as suspicious are nonetheless shipped before it can be determined that they are unlikely to be diverted.[5] Congress has recently ratified this construction.[6] And, the federal MDL court adopted this construction as well.

At trial, Plaintiffs will demonstrate that the Defendants failed to meet their statutory and regulatory duties, and that their failure was a contributing cause of the opioid epidemic in Huntington and Cabell County. On this motion, Plaintiffs ask that the Court issue an order clearly delineating what those statutory and regulatory duties are, in order to clarify the issues for trial.

LEGAL STANDARD

Rule 56 provides that "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."[7] Rule 56 permits a party to move for summary judgment on a claim or defense or on a "part of [a] claim or defense."[8] The

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[5] *See Masters Pharmaceutical, Inc. v. Drug Enforcement Administration,* 861 F.3d 206, 212-213 (D.C. Cir. 2017); *Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484 (Dep't of Justice July 3, 2007).

[6] *See* Public Law 115-271, § 3272.

[7] Fed. R. Civ. P. 56(a).

[8] *Id.*

rule thus "make[s] clear at the beginning that summary judgment may be requested not only as to an entire case but also as to a claim, defense, or part of a claim or defense."[9] "Statutory interpretation is a matter of law appropriate for resolution on summary judgment."[10]

ARGUMENT

I. THE CSA AND WVCSA DUTIES TO "MAINTAIN EFFECTIVE CONTROLS AGAINST DIVERSION" REQUIRE DISTRIBUTORS TO IDENTIFY AND REPORT SUSPICIOUS ORDERS AND TO HALT SHIPMENTS OF SUCH ORDERS PENDING INVESTIGATION

A. The Federal Controlled Substances Act Requires Distributors to Halt Shipments of Suspicious Orders Pending Investigation

The CSA sets forth as a primary factor in the grant of a registration to distribute controlled substances the "maintenance of effective controls against diversion . . . into other than legitimate . . . channels . . . ."[11] This provision has remained substantially unchanged since the enactment of the CSA in 1970. The requirement to maintain effective controls is further codified by the DEA at 21 C.F.R. § 1301.71(a), which provides that "[a]ll applicants and registrants shall provide

[9] Fed. R. Civ. P. 56, Advisory Committee Notes, subdivision (a) (2010).

[10] *Thomas v. Metro. Life Ins. Co.,* 631 F.3d 1153, 1160 (10th Cir. 2011); *see also Walsh v. United States,* 31 F.3d 696, 698 (8th Cir. 1994)(where an unresolved issue is "primarily legal rather than factual, summary judgment is particularly appropriate."); *Brown v. Smith,* 827 F.3d 609, 613 (7th Cir. 2016) (a "question of law" suitable for summary adjudication "typically concerns the meaning of a statutory or constitutional provision, regulation, or common law doctrine").

[11] 21 U.S.C.A. § 823(b)(1).

effective controls and procedures to guard against theft and diversion of controlled substances." This DEA requirement likewise has remained substantially unchanged since its adoption by the DEA in 1971.[12]

The duty to maintain effective controls against diversion is not merely a technical requirement. The regulatory scheme established by the CSA does not rely on the DEA to police shipments of controlled substances in the first instance, but rather it enlists registrants to do so and requires them to assume that task, in exchange for the privilege of dealing in dangerous narcotic drugs.[13] Moreover, the legislative history of the CSA shows that one of the fundamental purposes of the statute is to protect society from the dangers that controlled substances pose to the safety of communities.[14] As the DEA noted in revoking the registration of a distributor in *Southwood Pharmaceuticals*, "[r]espondent's distribution of 44 million dosage units of hydrocodone which were likely diverted caused extraordinary harm to the public health and safety."[15] Indeed, the DEA characterized the recipients of

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[12] *See Notice of Proposed Rulemaking: Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970,* 36 Fed. Reg. 4928 (Dep't of Justice Mar. 13, 1971)*; Final Rule: Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970,* 36 Fed. Reg. 7776 (Dep't of Justice Apr. 24, 1971).

[13] *See Southwood Pharmaceutical*, 72 FR 36487-01, 36504, 2007 WL 1886484 (Dep't of Justice July 3, 2007)(the DEA cannot all by itself "protect the American people from [the] extraordinary threat to public health and safety" posed by prescription narcotics; it "must rely on registrants to fulfill their obligation under the Act to ensure that they do not supply controlled substances to entities which act as pushers.").

[14] H.R. Rep. 91-1444, 4574, 4601-2 (1970).

[15] 72 FR 36487-01, 36503, 2007 WL 1886484.

the suspicious orders as "drug pushers operating under the patina of legitimate authority" and found that "[c]utting off the supply sources of these pushers is of critical importance in protecting the American people from this extraordinary threat to public health and safety."[16]

The DEA has construed the CSA to require registrants to design and operate a system to identify suspicious orders of controlled substances (the "identification duty"); to report to the DEA suspicious orders when discovered (the "reporting duty"); and to decline to ship an order identified as suspicious unless and until, through due diligence, the registrant is able to determine that the order is not likely to be diverted into illegal channels (the "no-shipping duty").[17] The first two of these duties, the identification and reporting requirements, are explicitly set forth at 21 C.F.R. § 1301.74, which provides that a registrant "shall design and operate a system to disclose to the registrant suspicious orders of controlled substances" and that the registrant "shall inform the Field Division Office of the Administration in his area of suspicious orders *when discovered by the registrant*."[18] The regulation defines suspicious orders to include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[19]

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[16] *Id.* at 36504.

[17] *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration,* 861 F.3d 206, 212-213 (D.C. Cir. 2017); *see also Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484.

[18] 21 C.F.R. § 1301.74(b)(Emphasis added).

[19] *Id.*

The no-shipping duty, while not set forth in the same express terms, is nonetheless inherent in the over-arching duty to maintain effective controls against diversion.[20] Indeed, in the federal MDL, the district court held not only that Distributors are under a duty "not to ship suspicious orders," *see In re Nat'l Prescription Opiate Litig.*, 2019 WL 3917575, but further held that:

> [G]iven the overriding duty of a registrant to maintain effective controls against diversion, the Court is hard-pressed to think of a more basic requirement than not to ship a dubious order bearing indicia that the drugs could be diverted to illegal channels. How can a registrant freely ship suspicious orders and still comply with its duty to maintain controls against diversion? It cannot. It has a duty not to ship the order unless due diligence reasonably dispels the suspicion.[21]

Thus, the MDL court granted the federal bellwether plaintiffs' motion for partial summary judgment with respect to the CSA duties of the manufacturers and distributors, the federal analog of this motion.

This Court should follow the MDL court and reach the same conclusion. The district court's conclusion is well-supported by the DEA's long recognition of the duty *not to ship* suspicious orders until they have been cleared through investigation.[22] As explained by the DEA in *Southwood Pharmaceuticals,* the no-shipping duty follows

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[20] *See Masters Pharmaceutical,* 861 F.3d 212-13.

[21] 2019 WL 3917575 at *9.

[22] *See Masters Pharmaceutical,* 861 F.3d at 212-13 ("Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order."); *Southwood Pharmaceuticals,* FR 36487-01, 36500, 2007 WL 1886484; *see also* DEA Rule 30(b)(6) Depo. (Prevoznik), Vol. 2, p. 771 (April 18, 2019) ("Q.: Does the DEA take the position that a registrant of controlled substances has a duty to block shipments of suspicious orders? A: Yes.") (Exhibit B).

directly from the statutory requirement that a registrant maintain effective controls against diversion. In *Southwood Pharmaceuticals,* the DEA revoked the registration of a distributor based primarily on the failure to maintain such controls. The DEA found that not only had Southwood failed to report suspicious orders, but also that it had failed to perform proper due diligence with respect to its customers, and that it had continued to ship to certain customers, even though the orders it shipped met the criteria to be considered "suspicious."[23] Indeed, the DEA found it "especially appalling" that, in light of the information available to it indicating that certain pharmacies to which it was shipping hydrocodone were engaging in diversion, Southwood "did not immediately stop distributing hydrocodone to any of the pharmacies."[24] The DEA noted "the threat to public safety posed by the diversion of controlled substances" and revoked Southwood's license, effective immediately, finding that "continued registration constituted an imminent danger to public health and safety."[25] Thus, Southwood's violation of the no-shipping requirement was one of the primary reasons its registration was revoked.

The DEA further and unequivocally removed any doubt about the existence of the no-shipping duty in letters it sent to opioid distributors in 2006 and 2007. In a September 27, 2006 letter, Joseph Rannazzisi, the Deputy Assistant Administrator in DEA's Office of Diversion Control, reminded distributors that in addition to an

[23] 72 FR 36487-01, 36498-99.

[24] *Id.* at 36500.

[25] *Id.* at 36504.

obligation to report suspicious orders, they had a "statutory responsibility to exercise due diligence to avoid *filling* suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[26] (Notably, this letter was sent approximately ten months before the administrative decision revoking Southwood's registration.) On December 27, 2007, Mr. Rannazzisi sent a second letter, in which the DEA once again reminded distributors that

> their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders *prior to completing a sale* to determine whether the controlled substances are likely to be diverted from legitimate channels."[27]

As the DEA letters make clear, and as explained in *Southwood Pharmaceutical*, the no-shipping duty is nothing more than an implementation of the basic duty to "maintain effective controls against diversion."[28] As the MDL court found, there can be no "effective controls against diversion" if a registrant is permitted to ship opioid orders it knows or should know bear the indicia of likely diversion. Thus, the no-shipping duty is not a later addition to the CSA or the regulations, but part and parcel of the original enactment. It is an "interpretive rule," which, rather than creating new duties, "simply states what the administrative agency thinks the statute means, and only reminds affected parties of existing duties."[29] The *Southwood Pharmaceutical* proceedings confirm this is so: if the duty

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[26] *See* 2006 Rannazzisi Letter (Exhibit C at *2)(emphasis added).

[27] 2007 Rannazzisi Letter (Exhibit D at *1)(emphasis added).

[28] *See* FR 36487-01, 36498-502, 2007 WL 1886484.

[29] *Tennessee Hosp. Ass'n v. Azar*, 908 F.3d 1029, 1042 (6th Cir. 2018).

had not already existed, Southwood would not have lost its registration for failing to comply with it.

DEA's construction – and that of the federal court – is plainly correct that *effective* control against diversion cannot be maintained if suspicious orders are shipped without investigation. Suspicious orders are, by definition, orders that that bear some indicia of diversion activity, including unusual size, unusual patterns, and/or unusual frequency.[30] They are orders that raise sufficient concerns about diversion that they must be reported to the DEA.[31] It is therefore reasonable to conclude that shipping suspicious orders without further investigation will not be an effective means to prevent diversion. Indeed, the construction recognizes that the registrants are partners with the DEA in the prevention of diversion, and that reliance on the DEA alone to prevent diversion using the information reported to it would not be a system of effective controls.[32]

That this construction of the CSA is correct has also been confirmed by Congress. On October 24, 2018, Congress enacted Public Law 115-271, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the "SUPPORT Act"). Among other provisions, the SUPPORT

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[30] 21 C.F.R. § 1301.74(b); W. Va. C.S.R. § 15-2-5.3 (previously W.Va. C.S.R. § 15-2-4.4).

[31] *Id.*; *see also* 2006 Rannazzisi Letter at *2 (The regulation also requires that the registrant inform the Field Division Office of the Administration in his area "of suspicious orders *when discovered* by the registrant.") (emphasis in original).

[32] *See Southwood Pharmaceutical,* 72 FR 36487-01, 36504, 2007 WL 1886484.

Act amended 21 U.S.C. § 827 so as to provide manufacturers and distributors with access to data from the Automated Reports and Consolidated Orders System ("ARCOS").[33] As the SUPPORT Act explains, "The purpose of this chapter is to provide drug manufacturers and distributors with access to anonymized information through the Automated Reports and Consolidated Orders System to help drug manufacturers and distributors identify, report, *and stop* suspicious orders of opioids and reduce diversion rates."[34] But the SUPPORT Act goes even further – the statute also provides a "Rule of Construction" explaining that "Nothing in this chapter should be construed to absolve a drug manufacturer, drug distributor, or other Drug Enforcement Administration registrant from the responsibility of the manufacturer, distributor, or other registrant to— (1) identify, *stop*, and report suspicious orders; or (2) maintain effective controls against diversion. . . ."[35]

Congress thus made crystal clear that the purpose of this particular provision of the SUPPORT Act is to give registrants additional tools – in the form of ARCOS data – to carry out their CSA duties, *including the duty to stop shipments*, and that the provision of these tools (or any previous lack of access to them) does not in any way absolve registrants of their statutory and regulatory duties, *including the existing duty to stop suspicious orders.*

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[33] *See* 21 U.S.C. § 827(f).

[34] PL 115-271, § 3272 (emphasis added).

[35] *Id.* (emphasis added).

In so doing, it is clear that Congress was aware of the DEA's construction of "effective controls against diversion" and intended to ratify it. "Subsequent legislation declaring the intent of an earlier statute is entitled to great weight in statutory construction."[36] It is also significant that, in ratifying the DEA's construction of the CSA, Congress did not amend the CSA to impose more explicitly the no-shipping requirement. This court can reasonably infer that Congress did not expressly impose this duty because it understood that the duty *already* existed under the CSA, and that it was necessary only to make clear how the provisions of the SUPPORT Act might affect that duty.[37]

DEA's construction of the CSA and the regulations would, even without the confirmatory legislation, be entitled to substantial deference.[38] Congress left it to the DEA to determine what constitutes "effective control against diversion," and DEA has made a reasonable determination of what is required. Moreover, as the Fourth Circuit has explained, in assessing an agency construction, reviewing courts are required to "afford controlling weight to an agency's reasonable interpretation even where we would have, if writing on a clean slate, adopted a different interpretation."[39]

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[36] *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 380-81, (1969).

[37] *See Heckler v. Turner*, 470 U.S. 184, 211 (1985) (clarification in subsequent legislation of existing statute not only "leaves no doubt as to the prospective interpretation of the statute, but it carries in addition considerable retrospective weight").

[38] *See Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843-44 (1984) ("considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer"".

[39] *Nat'l Elec. Mfrs. Ass'n v. U.S. Dep't of Energy*, 654 F.3d 496, 505 (4th Cir. 2011).

Rather, it is sufficient that the interpretation is a reasonable one.[40] Indeed, a court "may not disturb an agency rule unless it is arbitrary or capricious in substance, or manifestly contrary to the statute."[41] Congress's 2018 recognition of the no-shipping requirement adds even greater force to the deference that would usually be accorded to an agency interpretation, and leaves no room for doubt that, in order to carry out the statutory mandate to "maintain effective controls against diversion," a registrant may not ship suspicious orders that have not been cleared through investigation. It must, instead, block those orders until it can determine that diversion is unlikely.

Based on these same arguments, Judge Polster found that:

> The plain language of Section 1301.74 clearly requires that, upon discovery, registrants must identify and report suspicious orders to the DEA. As a regulation promulgated pursuant to Congressional authority, Section 1301.74 is legislative in nature and has the full force and effect of law. Accordingly, the Court finds that, as a matter of law, Section 1301.74 imposes a legal duty on registrants to: (1) design and operate a system to disclose to the registrant suspicious orders; and (2) inform the DEA of suspicious orders when discovered by the registrant…[T]he CSA statutory and regulatory duties to maintain effective controls against diversion includes a duty not to ship suspicious orders.[42]

As set forth in Plaintiffs' Memorandum of Law in Support of Motion to Adopt Multidistrict Litigation Court's Order on Defendants' Controlled Substances Act Duties, Judge Polster's ruling provides the legal framework for Defendants'

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[40] *Id. (*citing *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.,* 545 U.S. 967, 986, 125 S.Ct. 2688, 162 L.Ed.2d 820 (2005)).

[41] *Mayo Found. for Med. Educ. & Research v. United States*, 562 U.S. 44, 53 (2011); *see also Kar Onn Lee v. Holder*, 701 F.3d 931, 936 (2d Cir. 2012) (court "must defer" to agency interpretation if it is reasonable).

[42] Doc. 2483 at *12-19.

obligations under federal law and should be adopted under the law of the case doctrine.[43] However, even apart from the law of the case considerations, Judge Polster's reasoning is highly persuasive and should be adopted on its merits.

B. West Virginia's Controlled Substances Act Imposes the Same Requirement

The West Virginia Controlled Substances Act ("WVCSA") is intended to be consistent with the federal CSA to the fullest extent practicable.[44] The WVCSA, adopted in 1971, is derived from the Uniform Controlled Substances Act of 1970 ("UCSA").[45] The UCSA, in turn, is similar to its federal counterpart, the CSA, and "was drafted to achieve uniformity between the laws of the several States and those of the Federal government.[46]

The West Virginia Legislature enacted the West Virginia Wholesale Drug Distribution Licensing Act of 1991 ("DDLA"), W. Va. Code § 60A-8-1 et seq. [1991], to protect the health, safety, and general welfare of residents of this state. The West Virginia Board of Pharmacy was granted the power to promulgate rules "as may be necessary to carry out the purposes and enforce the provisions of the DDLA which

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[43] Doc. 189 at *1 and Doc. 190 at *4-12.

[44] *See* W.Va.Code 60A–6–603 [1971] (the UCSA "shall be so applied and construed as to effectuate its general purpose to make uniform the law with respect to the subject of this [Act] among those states which enact it."). The West Virginia Board of Pharmacy has adopted, by reference, the requirements of the federal regulations, 21 CFR Parts 1300-1321, and 21 U.S.C. 801. W. Va. C.S.R. § 15-2-2, superseded by W. Va. C.S.R. § 15-2-3 (Apr. 1, 2020).

[45] *State v. Young,* 185 W. Va. 327, 335, 406 S.E.2d 758, 766 (1991).

[46] *Id.* Uniform Controlled Substances Act of 1970 prefatory note, vol. 9, part II, *U.L.A.* 2 (1988).

shall conform to wholesale drug distributor licensing guidelines formally adopted by the food and drug administration at 21 C.F.R. Part 205."[47]

The WVCSA law provides that one of the qualifications for controlled substances licensure is that an applicant operate "in compliance with all federal legal requirements applicable to wholesale drug distribution."[48] The State Board of Pharmacy ("Board") regulations define a "registrant" as "a person who has obtained a controlled substance permit from the Board."[49] Thus, distributors are clearly included within the meaning of registrant.

Under the WVCSA, an applicant for a license to manufacture or distribute controlled substances is required to demonstrate that it provides "effective controls and procedures to guard against theft and diversion of controlled substances."[50]

West Virginia state law further imposes a duty upon the Supply Chain Defendants to design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the West Virginia Board of Pharmacy of suspicious orders when discovered "by providing a copy of the information which the wholesale drug distributor provides to the U.S. Drug Enforcement Administration

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[47] See W. Va. Code § 60A-8-9.

[48] W. Va. Code § 60A-8-7(c)(1)(I).

[49] The West Virginia Uniform Controlled Substance Act requires "every person who manufactures, distributes, or dispenses any controlled substance within this state" to "obtain annually a registration issued by the state board of pharmacy." W. Va. Code § 60A-3-302(a); *see also* W.Va. C.S.R. § 15-2-3, superseded by W.Va. C.S.R. § 15-2-4.1.1 (Apr. 1, 2020).

[50] W. Va. C.S.R. § 15-2-4.2.1, superseded by W. Va. C.S.R. § 15-2-5.1.1 (Apr. 1, 2020).

regarding such suspicious orders."[51] Suspicious orders include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[52]

The definition of "suspicious orders" is identical to the definition found in the federal regulations discussed above. Shipment of such orders without a determination that diversion is unlikely no more provides "effective controls against diversion" within the meaning of the WVCSA than it does within the meaning of the federal regulatory scheme. Licensees under the WVCSA are required to demonstrate compliance with the federal CSA, so that, in effect, the requirements of federal law are incorporated into the West Virginia statute as well.[53] For this reason, this Court can readily find that a violation of the federal "no-shipping" requirement also violates the WVCSA.

CONCLUSION

For the foregoing reasons, this Court should rule that the CSA and the WVCSA impose an obligation to maintain effective controls against diversion, and that in order to meet this obligation, distributors of controlled substances must design and operate a system to identify suspicious orders; must report suspicious order to the DEA; and must stop shipment of suspicious orders pending investigation.

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[51] W.Va. C.S.R. § 15-2-4.4, superseded by W. Va. C.S.R. § 15-2-5.3 (Apr. 1, 2020).

[52] *Id.*

[53] State law provides that one of the qualifications for licensure is that an applicant operate "in compliance with all federal legal requirements applicable to wholesale drug distribution." W. Va. Code § 60A-8-7(c)(1)(I).

Dated: September 22, 2020

Respectfully submitted,

THE CITY OF HUNTINGTON
/s/ *Anne McGinness Kearse*
Anne McGinness Kearse
WVSB No. 12547
Joseph F. Rice
MOTLEY RICE LLC
28 Bridgeside Blvd.
Mount Pleasant, SC 29464
Tel: 843-216-9000
Fax: 843-216-9450
akearse@motleyrice.com
jrice@motleyrice.com

Linda Singer
David I. Ackerman
MOTLEY RICE LLC
401 9th Street NW, Suite 1001
Washington, DC 20004
Tel: 202-232-5504
Fax: 202-386-9622
lsinger@motleyrice.com
dackerman@motleyrice.com

Charles R. "Rusty" Webb
WV No. 4782
THE WEBB LAW CENTRE
716 Lee Street, East
Charleston, West Virginia 25301
Telephone: (304) 344-9322
Facsimile: (304) 344-1157
rusty@rustywebb.com

CABELL COUNTY COMMISSION
/s/ *Paul T. Farrell, Jr.*
Paul T. Farrell, Jr.
WVSB Bar No. 7443
FARRELL LAW
422 Ninth Street, 3rd Floor (25701)
PO Box 1180
Huntington, West Virginia 25714-1180
Mobile: 304-654-8281
paul@farrell.law

/s/ *Anthony J. Majestro*
Anthony J. Majestro
WVSB No. 5165
POWELL & MAJESTRO, PLLC
405 Capitol Street, Suite P-1200
Charleston, WV 25301
304-346-2889 / 304-346-2895 (f)
amajestro@powellmajestro.com

Michael A. Woelfel
WVSB No. 4106
WOELFEL AND WOELFEL, LLP
801 Eighth Street
Huntington, West Virginia 25701
Tel. 304.522.6249
Fax. 304.522.9282
mikewoelfel3@gmail.com

CERTIFICATE OF SERVICE

I hereby certify that on September 22, 2020, a copy of the foregoing **PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT CONCERNING DEFENDANTS' STATUTORY AND REGULATORY DUTIES** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system. This filing will also be served on all parties by email to Track2OpioidDefendants@reedsmith.com, MDL2804Discovery@motleyrice.com and CT2_Opioid_Team@mail-list.com

/s/ *Anthony J. Majestro*